

## **Initiative that modifies the Official Mexican STANDARD NOM-072-SSA1-2012, Labeling of medicines and herbal remedies.**

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### **Reason.**

Improper use of antibiotics is a health risk and a waste of resources from medical services. Likewise, it increases the bacterial resistance which brings with it an increase in the hospital stay of the patients, in the cost of the treatments and the mortality in the population. Different initiatives around the world have been promoted, for example, the Mexican government modified the constitution following the recommendations of the World Health Organization. One of the most important modifications made by the Mexican government was to ask for a prescription for the sale of antibiotics. However, the control of this type of medication has not been rigorous and there are no records that help to know the reality of that problem. In order to address all the deficiencies in the country, modifications were made to the education and management systems of the national health sectors, however, it was not possible to generate an impact on the entire public or a concise national strategy. Antibiotic resistance and its inappropriate use are persistent problems of health systems, although several strategies to contain them have been implemented

### **Problematic**

One of the main problems with medicines is the improper use of these, one of the main causes is that in our country there are no inserts in the packaging of medicines that are sold by prescription, including antibiotics, which generates that Consumers do not have enough information when they are taking a prescribed medication.

The **norm NOM-072-SSAI-2012** is responsible for regulating the information contained in medicines and herbal remedies. Article 7.3 establishes that: "in the case of antibiotics and medications classified in sections V and VI of article 226 of the General Health Law, information directed to provide guidance on the correct use of the medication may be included."

As such, the wording of this article frees companies from the obligation to add informative inserts in the labeling of medicines, with this, patients cannot access any type of information on the antibiotics they consume, the above increases the effects negatives of self-medication. These effects could generate adverse reactions to patients and in the case of antibiotics it leads to a serious public health problem, which is resistance to them.

Antibiotic resistance is a major threat to public health. Its effects translate into an increase in hospital stay, cost of treatments and mortality. Inappropriate use of antibiotics is a situation that leads to increased resistance. There are a lot of factors that increase this problem. An average patient does not usually use antibiotics in an appropriate way since they do not take their full treatment and become self-medicated because of the lack of information they have available, or false information from different websites.

Improper use of medicines has negative consequences for both the health and the economy of those who consume it. Above all, the misuse of antibiotics generates bacteria resistant to them, consequently the effectiveness of existing treatments decreases, while costs and mortality increase.

Although antibiotics are a topic of interest to the Mexican health system, not much has been documented about them. In the country, very little information has been generated that allows us to know in depth the situation of this problem.

Antibiotics are among the most sold and consumed medications in Mexico. Its annual market reaches 960 million dollars and represents 14.3% of sales in private pharmacies in the country. As a result of these high sales, the Mexican market is one of the largest worldwide. To sum up, this market is very large and its inappropriate handling can leave consequences just as big.

One of the most encountered problems in Mexico is bacterial resistance in hospitals and in the community in general. For example, about 55% of the organisms that cause infections such as pneumonia or meningitis in Mexico are resistant to antibiotics. In addition to the above, there is also a record of resistant pathogens that cause enteric and urinary infections. This resistance results in an increase in mortality in the intensive care area of hospitals.

In monetary terms, inappropriate antibiotic use accounts for 11% of public health spending. This expense is caused by incorrect prescriptions and a lack of follow-up of treatments by patients. In addition, incorrect medication prescriptions come to represent 1 or 2 percent more of the patient's minimum daily salary. Bad prescriptions come to represent a large economic spillover that affects the Mexican economy.

As for legislation, in 2010 a law came into force that requires the sale of antibiotics only by prescription. The purpose of this law is to regulate the sale of this type of medication and ensure that the situation in which it is used has been analyzed by a professional, which was prepared following some of the recommendations made by the World Health Organization. However, this law does not contemplate the reality facing Mexico, which causes its effect to be reduced. Such a law is affected in third world countries since many times patients do not have money to go to the doctor to

be prescribed medication. Low-income patients are forced to self-medicate, due to a lack of resources. In conclusion, this is a law with positive effects such as greater control of antibiotics and negative effects such as increased self-medication.

Some Mexican regulations are intended to regulate medications in Mexico and reduce the effects of their inappropriate use. However, as explained at the beginning, these rules are not effective because they allow pharmaceutical companies to be released from any responsibility and are not applied as they should.

In Mexico, a large part of the strategies implemented has been in the area of education and directives of the health sector. First, training on prescriptions in medical schools began to improve. This sought to improve prescriptions for respiratory and stomach infections. Similarly, the use of clinical guidelines for better prescriptions in public health institutes was encouraged. There is a study that talks about the results of the implementation of these techniques. However, there are no studies that prove the effectiveness of these measures. In short, it has sought to improve prescriptions in Mexico, but it is not known if it is working.

Another measure implemented was the creation of epidemiological surveillance networks in hospitals. These networks reach more than 170 hospitals and monitor the use of antibiotics. Although there are many organizations looking for better use of antibiotics, the quality of their work usually varies. The variation in its quality makes the general monitoring of the problem less efficient. In addition, there is no information on the impact of these programs and how they work.

As for the sale of antibiotics, pharmacies and dispensaries have begun to prepare more throughout the country. The institution in charge of this program is the “Federal Commission for Protection against Health Risks”. The program seeks to raise awareness and offer more tools so that employees can help mitigate drug resistance. At the same time, campaigns have been made to create effective self-medication. For example, information campaigns on television have been made and information on the packaging of free-of-sale products has been increased. In conclusion, campaigns have already been implemented so that citizens know about the problem, but none has been directly focused on antibiotics.

Our proposal is to modify the wording of article 7.3 of Official Mexican Standard NOM-072-SSA1-2012, Labeling of medicines and herbal remedies, in order to establish the obligation to include informational inserts in antibiotics and the rest of the medicines referred to in section V and VI of article 226 of the general health law. This clear information is intended to give more access to society to make efficient use of medicines.

## **Background**

The large investments that have to be made to bring a new drug to the market can be wasted if patients do not make proper use of them. In places such as Europe, Australia and the US, the need to provide clear and appropriate information for the consumption of medicines has been stressed. In these places, it has been determined that clear and efficient information allows the user to administer their medications efficiently.

In Australia, new medicines are required to contain "Consumer Medicines Information" (CMI). This information is written by the pharmacists and the content must be consistent with the medication information. In that country, the law requires that there be a CMI for all medicines that require a prescription, however, there is no law that requires them to supply it in each prescription. New Zealand has followed Australia's model closely only that the development of WCC is not a requirement of law.

In the United States, there is a voluntary system of medication inserts in medications. This information is shorter than that offered by European countries or Australia and its method of delivery is through printed sheets in pharmacies. There is an exception to this voluntary system, which requires the provision of information to patients about medications that the FDA considers public health risks.

Directive 92/27 entered into force in the 1990s, which is a law of the European Union that requires all medicines to have a brochure with comprehensive information within them. "Comprehensive information" should have medication specifications, precautions, and contraindications. Before this law, some countries such as Holland, France, and Germany had their own system with informative inserts for medicines.

### **Legal basis**

Article 7.3 of Official Mexican Standard NOM-072-SSA1-2012, Labeling of medicines and herbal remedies that states the following: "In the case of antibiotics and medicines classified in sections V and VI of article 226 of the General Law Health information may be included to guide the correct use of the medicine. "

Article 226 of the General Health Law, sections V and VI establishes that it is:

V. Non-prescription drugs, authorized for sale exclusively in pharmacies.

SAW. Medicines that do not require a prescription to be purchased and can be dispensed in establishments other than pharmacies.

### **Proposed text**

"In the case of antibiotics and medications classified in sections V and VI of article 226 of the General Health Law, information aimed at providing guidance on the correct use of the medication should be included."

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